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MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: **PP# 4F4337/4H5700 - IMIDACLOPRID (GAUCHO®) ON BARLEY, WHEAT, SORGHUM, AND SUGARBEETS FOLLOWING SEED TREATMENT.** Review of the Residue Data and Analytical Method. (MRID #s 431756-01 and -02, 431592-01 thru -07)[CBTS #s 13494 thru 13497, and 14344]{DP Barcodes D201536, 201543, D201634, D201635, and D207206}

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and

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Thru: Richard A. Loranger, Ph.D., Acting Chief
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R. Loranger

INTRODUCTION

Gustafson, Inc., proposes tolerances for combined residues of the insecticide imidacloprid, trade named Gaucho® and Admire® (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine) and its metabolites, expressed as imidacloprid in or on the following raw agricultural commodities (racs): wheat forage at 7 ppm, wheat straw at 0.3 ppm, and wheat grain at 0.1 ppm; barley forage at 1.2 ppm, barley straw at 0.2 ppm, and barley grain at 0.1 ppm; sorghum forage, straw, and grain at 0.1 ppm; and sugar beet roots and tops at 0.1 ppm. A feed additive tolerance (FAT) is proposed for sugar beet molasses at 0.2 ppm.

EXECUTIVE SUMMARY OF RESIDUE CHEMISTRY DEFICIENCIES

- REVISED AND ADDITIONAL LABELS
- ADDITIONAL METHOD VALIDATION DATA
- ADDITIONAL CROP FIELD TRIAL DATA
- REVISED TOLERANCES
- ADDITIONAL DATA ON WHEAT AND SUGARBEET PROCESSING STUDIES

CONCLUSIONS

1. CBTS Conclusion on **Product Chemistry/Chemical Identity**

CBTS concludes that after reviewing the CSF for the TGAI the impurities present in the TGAI imidacloprid are not expected to be a residue problem in the subject crops wheat, barley, sorghum, and sugar beets when Gaucho® is used as directed for seed treatments. Analysis of various batches of the TGAI imidacloprid did not reveal any volatile N-nitroso amines to the limits of detection.

2. CBTS Conclusions on **Directions for Use**

a. The petitioner has proposed an adequate set of directions for use of imidacloprid formulated as Gaucho® 480 F for use as a seed treatment on wheat, barley, sorghum, and sugarbeets; and as Gaucho® ST for use as a seed treatment on sugarbeets. CBTS will translate the magnitude of the residue data from the Gaucho ST formulation to support the use of the Gaucho 480 F formulation as both are water soluble formulations.

b. The petitioner does not have to propose a new label and directions for use of Gaucho® 240 FS as CBTS considers both the Gaucho 480 F and Gaucho 240 FS to be water based flowable suspensions differing only in the amount of the active ingredient present.

c. The petitioner is not required to propose a set of directions for use of imidacloprid on sorghum seeds on a label for Gaucho® 70% HB, a graphite based non-dilutable powder. However, CBTS will consider all of the sorghum crop field trial data generated from use of the 70% HB formulation to be supplementary supporting data. CBTS declines to use the 70% HB sorghum crop field trial data to support the proposed total imidacloprid tolerance on sorghum from the use of 480 F (a water based flowable suspension formulation).

d. The petitioner has proposed an adequate set of directions for use of Gaucho® 75 ST for use as a seed treatment on sugar beets.

e. For the Gaucho 480 F and the Gaucho 75 ST labels the petitioner has not proposed adequate rotational crop restrictions. CBTS concludes that detectable residues were noted at eleven months rotational interval; thus the labels need to have a 12 month plant back interval for all crops that do not have tolerances and registered uses. Since detectable residues at the MDL were noted in the turnip roots at 11 months, an 8 month plant back interval is not supportable. CBTS considers a 30 days plant back for grain only without the grower being allowed use of the forage, vines, or straw to be impractical. It is not practical to restrict growers to using only part of their crop. We feel this would be extremely difficult to enforce, thus should not be on the label.

f. If the petitioner wishes to have shorter than 12 months plant back intervals for grains, seeds, and/or root crops, then he may generate the necessary rotational crop magnitude of the residue data to support rotational crop tolerances. At this time the lowest level validated for a rotational crop tolerance using Bayer method 0200 would be 0.05 ppm.

g. If the petitioner wishes, then CBTS has no objections to a proposal for rotational crops that allows treated areas, including areas planted with treated seeds, to be replanted with any crop for which there are registered uses and established tolerances.

3. CBTS Conclusion on the **Nature of the Residue - Plants**

The nature of the imidacloprid residue in apples, potatoes, tomatoes, eggplant, cottonseed, and in corn grain, forage, and fodder is adequately understood. The residues of concern are combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid. CBTS is translating all of these data to wheat, barley, sorghum, and sugarbeets.

4. CBTS Conclusion on the **Nature of the Residue - Livestock**

The nature of the imidacloprid residue in ruminants and poultry is adequately understood. The residues of concern are combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid.

5. CBTS Conclusion on **Confined Rotational Crops**

The registrant has adequately characterized and identified the nature of the imidacloprid residue in rotational crops. The nature of the residue in rotational crops is adequately understood and is nearly identical to that identified in the primary crops. While total imidacloprid residues were greater than 0.01 ppm from a 1X application indicating a potential for inadvertent residues to occur in non-target crops planted in rotation, CBTS concludes this is not an issue in this petition as the registrant has presented adequate limited field rotational crop studies that indicate with a 12 month plant back interval, rotational crop tolerances are not necessary as total imida-

cloprid residues are expected to be below the MDL (minimum limit of detection).

6. CBTS Conclusions on the **Residue Analytical Method**

a. An adequate interference study has been presented which shows a positive interference will occur from only clopyralid when using Bayer method 00200.

b. Adequate multiresidue method (MRM) recovery data for imidacloprid and its olefin, hydroxy, guanidine, and 6-chloronicotinic acid (6-CNA) metabolites through FDA's Protocols A through E have been presented. These data have been forwarded to FDA for publication in a future update in PAM, Vol I.

c. Bayer method 0200 has been presented to gather the magnitude of the residue data in plants and their processed commodities, and to enforce the proposed tolerances. Bayer method 00191 has been presented to gather magnitude of the residue data in milk, meat, poultry, and eggs; and to enforce the secondary tolerances in these commodities. Both of these methods are common moiety methods that use a methanol/dilute sulfuric acid extraction, filtering through celite/filter paper, resin column clean-up, permanganate oxidation of parent and metabolites to 6-CNA, MSFTA derivatization, and determination in a capillary GC-MS selective ion monitoring at m/z 214, 216, 170, and 140.

d. For this and the co-pending petitions the lack of a confirmatory procedure is not a bar to our recommendation for the proposed tolerances, provided no other compounds in this new class of insecticides that have their residues determined as 6-CNA are presented for registration and tolerances while this petition is under review. CBTS reiterates that a confirmatory method is needed that precisely identifies imidacloprid and its metabolites. The method needs to be semi-quantitative, though we prefer the method be quantitative. The registrant is encouraged to continue the HPLC method development that measures imidacloprid as imidacloprid and separately measures its major metabolites, and to present the Agency with the completed validated HPLC method and accompanying ILV data as soon as possible. CBTS reiterates its observation that the registrant needs to keep the lab time of the HPLC method under 2 days as this is necessary for the method to be an effective enforcement procedure.

e. Method and concurrent validation data for Bayer method 00200 from wheat and wheat processed commodities, barley, sorghum and sorghum processed commodities, and sugar beets and sugar beet processed commodities were presented.

f. Tolerance method validations (TMVs) were requested for Bayer methods 00191 (residues in milk and tissues) and 0200 (residues in plants) for imidacloprid and its metabolites in milk and liver, and apples and cottonseed. The results of the successful method trials were reported by the Analytical Chemistry Branch. While ACB did not determine the methods' MDL (minimum detection

limit) its estimate of 0.02 ppm in both methods is supported by chromatographic data. Based on acceptable recoveries with supporting chromatographic data there have been successful TMVs for Bayer methods 00200 and 00191. The methods are marginally suitable to be enforcement methods with perishable commodities as both the ILV and EPA time frame to complete a set of samples takes approximately 20 hours or into a third working day. CBTS reiterates these methods are quite rugged and effective as enforcement procedures when very rapid turn around times are not required. They meet all other requirements of Subdivision O and will be forwarded to FDA for publication in PAM, Vol II.

g. The registrant has presented ILV data for both methods. The ILV data for the plant method using apples were generated by Ricerca and the ILV data for the animal tissues method using liver were generated by Huntingdon Analytical Services. The ILV data are acceptable and are in agreement with the registrant's method validation data as well as the data generated by the Agency's method trials. The data support methods 00200 and 00191 as being capable of enforcing the proposed tolerances. There are supplementary ILV data for the residues in plants method at the LOQ.

h. CBTS reiterates the comments of our April 20, 1993, letter from R.A. Loranger that the petitioner needs to generate additional method validation data at the LOQ of 0.05 ppm on all commodities in this petition for which magnitude of the residue data are presented. CBTS suggests the petitioner use the protocol proposed and accepted in a co-pending petition to provide the necessary recovery data at the proposed tolerances which involves a triplicate recovery of a mixture composed of equal amounts of the parent, and its guanidine, hydroxy, olefin, and 6-CNA metabolites (each compound at 0.01 ppm) from each grain commodity. The use of one control sample with each set of recoveries is acceptable.

i. With these additional recovery data at the LOQ of 0.05 ppm these new data will also serve as the necessary method validation data for the proposed tolerances on barley grain, wheat grain, sorghum grain, sorghum forage, sorghum fodder, sugar beet root, and sugar beet tops.

j. Since the petitioner has not provided any method validation data at the proposed tolerances CBTS reiterates that these additional method validation data are required on barley forage and straw, wheat forage and straw, and sugar beet molasses. Again CBTS suggests the petitioner use the protocol proposed and accepted in a co-pending petition to provide the necessary recovery data at the proposed tolerances on wheat forage at 7 ppm, on wheat straw at 0.3 ppm, and on sugar beet molasses at 0.2 ppm which involves a triplicate recovery of a mixture composed of 1/2 parent plus 1/4 each of the guanidine and olefin metabolites from each of these commodities. The use of one control sample with each set of recoveries is acceptable.

7. CBTS Conclusion on **Storage Stability**

Imidacloprid and its metabolites are stable in potatoes, apples, apple juice, and pomace; cottonseed, cottonseed hulls, soapstock, and oil as well as wheat grain, forage, and straw, and in wheat processed commodities at -20°C for at least 18-20 months. There are supplementary storage stability data that show imidacloprid and its metabolites both labeled and unlabeled are stable in lettuce under conditions of frozen storage for at least 24 months. These data are sufficient to support the magnitude of the residue crop field trial data for wheat, barley, sorghum, and sugar beets.

8. CBTS Conclusions on **Magnitude of the Residues - Crop Field Trials**

a. The petitioner needs to provide the wheat and barley seeding rate per acre so that we will be able to determine the rate of imidacloprid applied per acre for all of the 1991 wheat and barley field trials.

b. No wheat or barley hay samples were harvested and analyzed for total imidacloprid residues. For the 1991 and 1993 field trials we will not require wheat and barley hay residue data. CBTS will use a concentration factor of 3.52 to determine residues in wheat hay from wheat forage, and a 2.93 dry down factor to determine residues in barley hay from barley forage. For the 6 new imidacloprid wheat field trials and 4 new barley field trials the petitioner will need to present residue data for barley and wheat hay in additional to residue data from barley and wheat grain, forage, and straw. The petitioner will need to present along with the imidacloprid residue data on hay the percent moisture for each hay sample.

c. The petitioner did not provide adequate raw data, including an adequate number of copies of supporting chromatograms, for the 1993 imidacloprid barley, wheat, and sorghum crop field trial data. The petitioner needs to revise the 1993 reports to have the LOQ at <0.05 ppm and the MDL at 0.01-0.02 ppm for all samples of barley, sorghum, and wheat forage, grain, and straw/fodder. The petitioner is reminded that CBTS sets tolerances no higher than necessary. The raw data needed from the 1993 reports are the chromatographic counts for each sample, a copy of each chromatogram not already submitted as we feel from our review of the few chromatograms submitted that there are real residues of total imidacloprid present in treated sorghum forage, grain, and fodder; wheat forage and straw; and barley straw ranging from 0.02 ppm to 0.1 ppm. The raw data and copies of supporting chromatograms are needed so that we can independently verify the reported results.

d. CBTS declines to accept the 1993 imidacloprid barley, wheat, and sorghum crop field trial data as adequate to support the proposed imidacloprid tolerances on wheat grain, forage, and straw; on barley grain, forage, and straw; and on sorghum grain, forage, and fodder until we have reviewed the revised crop field trial reports. The petitioner is reminded that we set tolerances

no higher than necessary. Thus, the petitioner may have to propose in a revised Section F tolerances for barley grain, wheat grain, and sorghum grain at 0.05 ppm. The petitioner will need to propose total imidacloprid tolerances on barley hay and wheat hay once all of the crop field trial data are gathered. Judgement is deferred on the adequacy of the proposed imidacloprid tolerances at 0.1 ppm on wheat grain, 0.3 ppm on wheat straw, 7 ppm on wheat forage, 0.1 ppm on barley grain, 0.2 ppm on barley straw, 1.2 ppm on barley forage, and at 0.1 on sorghum forage, fodder, and grain until we have reviewed the revised 1993 crop field trial reports and the additional magnitude of the residue crop field trial data needed.

e. Total imidacloprid residues on aspirated wheat and sorghum grain fractions were not presented. However, since the proposed use is a seed treatment as opposed to a late season foliar or post harvest application CBTS will not require any imidacloprid residue data at this time for aspirated sorghum and wheat grain fractions. The petitioner/registrant is reminded that if there are additional uses proposed at a later date for either foliar application, or post harvest application to wheat and/or sorghum, then total imidacloprid residue data on aspirated grain fractions will need to be provided for both commodities.

f. The petitioner needs to present additional magnitude of the imidacloprid residue data on wheat from 6 additional trials as follows; one trial from Region 5, 2 trials from Region 7, and 3 trials from Region 8. Regions are defined in the June 1994 document "EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances."

g. The petitioner needs to present additional magnitude of the imidacloprid residue data on barley from 4 additional trials as follows: one trial from Region 5, 2 trials from Region 7, and 1 trial from Region 9.

h. The petitioner needs to present additional magnitude of the imidacloprid residue data on grain sorghum from 3 additional trials as follows: 2 trials from Region 5, and 1 trial from Region 8.

i. The petitioner needs to present additional magnitude of the imidacloprid residue data on sugarbeet tops and roots from 4 additional trials as follows: 2 trials from Region 5, 1 trial from Region 10, and 1 trial from Region 11.

j. The petitioner needs to revise the 1993 sugarbeet report to have the LOQ at <0.05 ppm and the MDL at 0.01-0.02 ppm for all samples of sugarbeet tops and roots. The raw data needed from the 1993 report are the chromatographic counts for each sample. We feel from our review of the chromatograms submitted that there are real residues of total imidacloprid present in treated sugarbeet tops and roots ranging from 0.01-0.02 ppm to 0.1 ppm. The raw data along with copies of supporting chromatograms are needed so that we can independently verify the reported results.

k. CBTS declines to accept the 1993 imidacloprid sugarbeet crop field trial data as adequate to support the proposed imidacloprid tolerances on sugarbeet tops and roots at 0.1 ppm until we have reviewed the revised crop field trial report. The petitioner is reminded that we set tolerances no higher than necessary. Thus, the petitioner may have to propose in a revised Section F a tolerance for sugarbeet roots at 0.05 ppm. Judgement is deferred on the adequacy of the proposed imidacloprid tolerances at 0.1 ppm on sugarbeet tops and roots until we have reviewed the revised 1993 crop field trial report and the additional magnitude of the residue crop field trial data needed.

9. CBTS Conclusion on **Rotational Crops - Field Accumulation Studies**

CBTS concludes that the petitioner has presented adequate limited field rotational crop studies from 3 sites with an in-furrow soil application of the 2.5% granular formulation and soil aged 1, 4, 8, and 11 months before replanting with the cereal grains wheat or sorghum, turnips as the root crop, and mustard greens or spinach as the leafy vegetable. Total imidacloprid residues were at or about the minimum detection limit (MDL) of 0.01 ppm by 11 months. CBTS would not expect total imidacloprid residues to be present after 12 months in cereal or small grains, root crops, or leafy vegetables. These limited field crop rotational studies with the 3 crop groups support an overall 12 month plant back restriction for no detectable residues to be present in rotated crops and that no rotational crop imidacloprid tolerances are necessary with such a restriction.

10. CBTS Conclusions on **Magnitude of the Residue - Processed Food/Feed**

a. The petitioner has conducted an adequate wheat processing study using wheat bearing detectable residues following an exaggerated 5X imidacloprid application to the seeds. However, the petitioner needs to present a revised final report recalculating the results based on a 0.05 ppm LOQ and a 0.01-0.02 ppm MDL as well as provide data on the seeding rate. Judgement is deferred in the results of this imidacloprid wheat processing study until we have received information on the seeding rate, reviewed the recalculated results and the petitioner's revised conclusions. CBTS expects that real residues of total imidacloprid may result in bran, shorts, and flour; and a FAT may be required.

b. The petitioner has conducted an adequate sugarbeet processing study using sugar beet bearing detectable residues following an exaggerated 2.68X imidacloprid application to the seeds. However, the petitioner needs to present a revised final report recalculating the results based on a 0.05 ppm LOQ and a 0.01-0.02 ppm MDL. Judgement is deferred on the results of this imidacloprid sugarbeet processing study until we have reviewed the recalculated results and the petitioner's revised conclusions. CBTS expects that there are real residues of total imidacloprid in dried sugarbeet pulp which may require a FAT. We also expect

that the FAT for imidacloprid in molasses will be significantly higher requiring a revised Section F.

c. There are no detectable total imidacloprid residues at or above the LOQ of 0.05 ppm in the rac sorghum grain from an exaggerated 2X seed treatment application of Gaucho, thus a sorghum processing study is not required. CBTS reiterates our comments of the April 20, 1993, letter where we agreed with the petitioner's conclusion that a sorghum processing study is not required. CBTS also points out that in Table II (June 1994) sorghum flour is listed as the only processed commodity from grain sorghum and we are not requiring residue data on sorghum flour at this time, thus no sorghum processing study is required.

d. As long as the petitioner has presented valid processing studies for the representative commodity wheat CBTS will not require an additional processing study for barley.

11. CBTS Conclusions on **Magnitude of the Residue - Meat/Milk/Poultry/ Eggs**

a. Based on the results of the imidacloprid bovine and poultry feeding studies, finite residues will occur in meat, milk, poultry, and eggs from the feeding of imidacloprid treated racs or their processed feed items when Admire®, and/or Gaucho® is used as directed in seed treatments. Adequate total imidacloprid secondary tolerances have been proposed in co-pending petitions at 0.1 ppm in milk, 0.3 ppm in meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep, 0.02 ppm in eggs, and 0.05 ppm in meat, fat, and meat by-products of poultry; but are not proposed in this petition.

b. Since there are major livestock feed items associated with the racs and their processed feed items in this petition the petitioner will need to propose in a revised Section F the same total imidacloprid secondary milk, meat, poultry and eggs tolerances that have been proposed in the co-pending petitions currently in reject status.

12. CBTS Conclusion on **Harmonization of Tolerances**

Since there are no Mexican, Canadian, or Codex MRLs/tolerances for total imidacloprid on wheat, barley, sorghum, sugar beets and their processed commodities, compatibility is not a problem at this time.

RECOMMENDATION

CBTS cannot recommend for the requested tolerances for combined residues of imidacloprid and its metabolites containing the 6-chloro-pyridinyl moiety, all expressed as imidacloprid on wheat forage at 7 ppm, wheat straw at 0.3 ppm, and wheat grain at 0.1 ppm; barley forage at 1.2 ppm, barley straw at 0.2 ppm, and barley grain at 0.1 ppm; sorghum forage, straw, and grain at 0.1 ppm; and sugar beet roots and tops at 0.1 ppm plus a feed additive tolerance (FAT) on sugar beet

molasses at 0.2 ppm for the reasons cited in our Executive Summary and further described in Conclusions 2e, 6h and j; 8a-d, f-k; 10a and b; and 11b.

For further consideration of this petition the company should be advised to resolve the deficiencies as described in our Conclusions above.

CBTS would have no objections to total imidacloprid tolerances with expirations dates (to be decided by RD) if and when the deficiencies relating to directions for use and processing studies are resolved and provided that the petitioner has presented acceptable protocols to generate the necessary residue analytical method validation data and the necessary additional crop field trials for barley, wheat, sorghum, and sugarbeets.

DETAILED CONSIDERATIONS

BACKGROUND

CBTS has recommended for a tolerance of combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid on mangoes at 0.2 ppm (see PP# 3F4285 memorandum by F. Griffith dated July 22, 1994).

There are two co-pending petitions currently in reject status. One permanent tolerance request for total imidacloprid residues on apples, cottonseeds, and potatoes, and their processed commodities, plus meat, milk, poultry, and eggs (see PP# 3F4169) has deficiencies remaining for additional residue method validation data at and above the proposed tolerance levels, and a revised set of directions for use on rotational crops (see memorandum by F. Griffith dated August 9, 1994). The other permanent tolerance request is for total imidacloprid residues in fruiting vegetables and the Brassica (cole) leafy vegetables crop groups, leaf and head lettuce, and grapes and grape processed commodities, plus meat, milk, poultry, and eggs (see memorandum in PP# 4F4231 dated August 11, 1994) has deficiencies remaining for additional residue method validation data at the proposed tolerance levels, a tomato processing study, and a revised set of directions for use on rotational crops.

CBTS recommended for imidacloprid Emergency Exemptions during 1993 on broccoli, cauliflower, cabbage, head and leaf lettuce, cotton, tomatoes, and potatoes. As of August 1, 1994, CBTS has recommended for additional imidacloprid Emergency Exemptions on cucurbits vegetables crop group (94TX0004), apples (94WA0002), peppers (94FL0003), oranges and grapefruit (94FL0005), potatoes (94OH0001), hops (94WA0012, 94OR0011, and 94ID0005), and tomatoes (94CA0020).

A SUMMARY of all plant and animal metabolism data were presented to the HED Metabolism Committee. The Committee concluded (see memorandom by F. Griffith dated June 24, 1993) that no additional plant or animal metabolism studies are needed at this time, the levels of the

nitrosimino compound in the TGAI are not of TOX concern, residues of the guanidine and nitrosimino imidacloprid metabolites plus other metabolites at the levels reported in the different metabolism studies are not toxicologically significant, no separate regulation of metabolites is warranted, and there is no scientific objection to the tolerance expression being for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety.

PRODUCT CHEMISTRY/CHEMICAL IDENTITY

No new imidacloprid product chemistry data were submitted for the TGAI in this petition. The product chemistry data for the TGAI were summarized in our initial reviews for PP#s 3F4169 and 3F4231. The registrant has adequately identified the active ingredient, described the starting materials, listed the sources for each, and described the manufacturing process, including the equipment used in the manufacturing process. A detailed discussion on the formation of impurities, both actual and theoretical has been presented and reviewed.

CBTS concludes that after reviewing the CSF for the TGAI the impurities present in the TGAI imidacloprid are not expected to be a residue problem in the subject crops wheat, barley, sorghum, and sugar beets when Gaucho® is used as directed as a seed treatment. Analysis of various batches of the TGAI imidacloprid did not reveal any volatile N-nitroso amines to the limit of detection.

DIRECTIONS FOR USE/LABELING

Imidacloprid is proposed for use as an insecticide to provide early season protection against sucking insects, such as aphids, chinch bugs, Hessian fly, thrips, and wireworms.

In this petition proposed use of 2 formulations to treat various seeds prior to planting. One label is for Gaucho® 480 Flowable (EPA File Symbol 7501-RLL) containing 4 lbs active ingredient (a.i.) imidacloprid per gallon or 40.7% ai and the other label is for Gaucho® 75 ST (EPA File Symbol 7501-) containing 75% ai imidacloprid.

For use on barley and wheat seed only apply at a rate of 1.5 to 3 fluid ozs (0.05 to 0.1 lb imidacloprid) of Gaucho® 480 Flowable to 100 lbs of seed prior to planting as a slurry treatment to ensure through treatment. For use on sorghum seed only apply at a rate of 4 to 8 fl ozs (0.125 to 0.25 lb imidacloprid) of Gaucho® 480 F to 100 lbs of seed prior to planting as a slurry treatment to ensure through coverage. For use on pelleted sugar beet seed apply at a rate of 6.3 fl ozs (0.2 lb imidacloprid) of Gaucho® 480 F to approximately 1 kg of raw seed. Sugar beet seed must be pelleted at a weigh-weigh ratio of 2:1 pelleted mixture to raw seed.

Restrictions on the Gaucho® 480 F label are do not graze or feed livestock on treated fields of barley and wheat for 60 days after planting, and for 45 days after planting sorghum. Treated seeds must not be used for or mixed with food or animal feed or processed for oil. Imidacloprid commercially treated wheat, barley, sorghum, and

sugar beets seeds must be properly labeled and easily identified as treated seeds.

The petitioner has proposed an adequate set of directions for use of imidacloprid formulated as Gaucho® 480 Flowable for use as a seed treatment on barley, wheat, sorghum, and sugarbeets; and as Gaucho® ST for use as a seed treatment on sugarbeets. CBTS will translate the magnitude of the residue data from the Gaucho ST formulation to support the use of the Gaucho 480 F formulation on sugarbeets as both are water soluble formulations.

CBTS notes that the petitioner has conducted all of the required magnitude of the residue crop field trials on barley and all but one of the wheat crop field trials using imidacloprid formulated as Gaucho 240 FS. The petitioner does not have to propose a new label and directions for use of Gaucho® 240 FS as CBTS considers both the Gaucho 480 F and Gaucho 240 FS to be water based flowable suspensions differing only in the amount of the active ingredient present.

For use on grain sorghum seed the petitioner conducted additional crop field trials using seed treated with Gaucho 480 F at a rate of 4 fl ozs (0.25 lb ai) per 100 lbs of seed, then overtreated just prior to planting with Gaucho® 70% HB at a rate of 4 oz ai (0.25 lb ai) per 100 lbs grain sorghum seed. The petitioner is not required to propose a set of directions for use on sorghum seeds for Gaucho® 70% HB, a graphite based non-dilutable powder. However, CBTS will consider all of the sorghum crop field trial data generated from use of the 70% HB formulation to be supplementary supporting data. CBTS declines to use the 70% HB sorghum crop field trial data to support the proposed total imidacloprid tolerance on sorghum from the use of 480 F (a water based flowable suspension formulation).

For use on pelleted or coated sugar beet seed only apply at a rate of 4.25 ozs (0.2 lb imidacloprid) of Gaucho® 75 ST to approximately 1 kg of raw seed. Sugar beet seed must be pelleted at a weigh-weigh ratio of 2:1 pelleted mixture to raw seed. The restrictions are that the treated seed must not be used for or mixed with food or animal feed or processed for oil. Imidacloprid commercially treated sugar beets seeds must be properly labeled and identified as treated seeds.

For the Gaucho 480 F and the Gaucho 75 ST labels the petitioner has not proposed adequate rotational crop restrictions. CBTS concludes that detectable residues were noted at eleven months rotational interval; thus the label needs to have only a 12 month plant back interval for all crops that do not have tolerances and registered uses. Since detectable residues at the MDL were noted in the turnip roots at 11 months, an 8 month plant back interval is not supportable. CBTS considers that a 30 days plant back for grain only without the grower being allowed use of the forage, vines, or straw to be impractical. It is not practical to restrict growers to using only part of their crop. We feel this would be extremely difficult to enforce, thus should not be on the label.

If the petitioner wishes to have shorter than 12 months plant back intervals for grains, seeds, and/or root crops, then he may generate the necessary rotational crop magnitude of the residue data to support rotational crop tolerances. At this time the lowest level validated for a rotational crop tolerance using Bayer method 0200 would be 0.05 ppm.

If the petitioner wishes, then CBTS has no objections to a proposal for rotational crops that allows treated areas, including areas planted with treated seeds, to be replanted with any crop for which there are registered uses and established tolerances.

NATURE OF THE RESIDUE - PLANTS

No new plant metabolism studies were submitted with this petition. The registrant has presented plant imidacloprid metabolism studies for apples, potatoes, tomatoes, eggplant, cottonseed, and corn. These studies have been previously reviewed in PP#s 3F4169 and 3F4231 (see memoranda by F. Griffith dated Sept. 21, 1993, and June 22, 1994).

In summary imidacloprid is metabolized by three pathways as follows:

1) hydroxylation of the dihydroimidazole ring of imidacloprid to form 4-hydroxy, 5-hydroxy, and dihydroxy imidacloprid followed by the loss of water to form the olefin imidacloprid,

2) reduction and loss of the nitro group on the dihydroimidazole ring to form the nitrosimino imidacloprid, then the guanidine imidacloprid, and finally the urea imidacloprid,

3) bridge cleavage of the C-N bond to form the 6-chloropicolyl alcohol (6-CPA), which rapidly forms the glucoside: 6-chloronicotinic acid (6-CNA), and the dihydroimidazole.

The imidacloprid corn metabolism study confirms that from imidacloprid treated seeds residues will translocate from the seeds to edible portion of the crop.

The nature of the imidacloprid residue in apples, potatoes, tomatoes, eggplant, cottonseed, and in corn grain, forage, and fodder is adequately understood. The residues of concern are combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid. CBTS is translating all of these data to wheat, barley, sorghum, and sugar beets.

NATURE OF THE RESIDUE - LIVESTOCK

No new ruminant or poultry imidacloprid metabolism studies were presented in this petition. The registrant has presented livestock imidacloprid metabolism studies for ruminants and poultry. These studies have been previously reviewed in PP#s 3F4169 and 3F4231 (see memoranda by F. Griffith dated Sept. 21, 1993 and June 22, 1994).

In summary, bovine imidacloprid metabolism follows four pathways as follows:

1) hydroxylation of the dihydroimidazole ring of imidacloprid to form 4-hydroxy, 5-hydroxy, plus the glucuronide conjugate of each monohydroxy metabolite, the dihydroxy imidacloprid followed by the loss of water to form the olefin imidacloprid,

2) reduction and loss of the nitro group on the dihydroimidazole ring to form the aminoguanidine imidacloprid, then the guanidine imidacloprid, and finally the urea imidacloprid,

3) opening of the dihydroimidazole ring with the loss of the ethyl group and subsequent oxidation. The first step is forming the nitroguanidine imidacloprid, next the ring open guanidine which can also form from both the guanidine imidacloprid and the dihydroxy guanidine imidacloprid. This metabolite can form picolylic urea and picolylic amine which is oxidized to 6-chloronicotinic acid (6-CNA),and then conjugates with glycine and,

4) a minor pathway involving the oxidative cleavage of the methylene bridge to form 6-CNA and its derivatives.

Poultry imidacloprid metabolism follows four similar, but not identical pathways with different metabolites as follows:

1) hydroxylation of the dihydroimidazole ring of imidacloprid to form the 4-hydroxy, 5-hydroxy, and the dihydroxy imidacloprid followed by the loss of water to form the olefin imidacloprid,

2) reduction and loss of the nitro group on the dihydroimidazole ring to form the dihydroxyguanidine imidacloprid,

3) opening of the dihydroimidazole ring with the loss of the ethyl group and subsequent oxidation. The first step is forming the nitroguanidine imidacloprid, next the ring open guanidine which can also form from both the guanidine imidacloprid and the dihydroxy guanidine imidacloprid. This metabolite can form picolylic urea and picolylic amine which is oxidized to 6-CNA and,

4) a minor pathway involving the oxidative cleavage of the methylene bridge to form 6-CNA and its derivatives.

The nature of the imidacloprid residue in ruminants and poultry is adequately understood. The residues of concern are combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid.

CONFINED ACCUMULATION STUDIES ON ROTATIONAL CROPS

No new confined accumulation rotational crop studies were presented in this petition. The registrant has presented confined accumulation rotational crop studies using ^{14}C-imidacloprid treated soil and planted with Swiss chard as the leafy vegetable, red beets as the root crop, and wheat as the cereal grain. These studies have been

previously reviewed in PP#s 3F4169 and 3F4231 (see memoranda by F. Griffith).

The registrant has adequately identified around 45% of the ^{14}C-imidacloprid residue from a 1X soil application and further characterized up to 91-96% of the residues in the rotational crops. The nature of the residue in rotational crops is adequately understood and is nearly identical to that identified in the primary crops. While total imidacloprid residues were greater than 0.01 ppm from a 1X application indicating a potential for inadvertent residues to occur in non-target crops planted in rotation, CBTS concludes this is not an issue in this petition as the registrant has presented adequate limited field rotational crop studies that indicate with a 12 month plant back interval rotational crop tolerances are not necessary as total imidacloprid residues are expected to be below the MDL (minimum limit of detection).

RESIDUE ANALYTICAL METHODS

An adequate interference study has been presented which shows a positive interference will occur from only clopyralid when using Bayer method 00200.

Adequate multiresidue method (MRM) recovery data for imidacloprid and its olefin, hydroxy, guanidine, and 6-chloronicotinic acid (6-CNA) metabolites through FDA's Protocols A through E have been presented. These data have been forwarded to FDA for publication in a future update in PAM, Vol I.

Bayer method 0200 has been presented to gather the magnitude of the residue data in wheat, barley, sorghum, and sugar beets and their processed commodities, and to enforce the proposed tolerances. Bayer method 00191 has been presented to gather magnitude of the residue data in milk, meat, poultry, and eggs; and to enforce the secondary tolerances in these commodities. Both of these methods are common moiety methods that use a 3:1 methanol/1% sulfuric acid extraction, filtering through celite/filter paper, XAD 4 resin column clean-up, oxidation of parent and metabolites to 6-CNA by refluxing in a 32% NaOH solution combined with a 5% $KMnO_4$ solution, extracted 3 times with methyl t-butyl ether, then MSFTA derivatization for 1 hour, and determination in a capillary GC-MS selective ion monitoring at m/z 214, 216, 170, and 140.

For this and the co-pending petitions the lack of a confirmatory procedure is not a bar to our recommendation for the proposed tolerances, provided no other compounds in this new class of insecticides that have their residues determined as 6-CNA are presented for registration and tolerances while this petition is under review. CBTS reiterates that a confirmatory method is needed that precisely identifies imidacloprid and its metabolites. The method needs to be semi-quantitative, though we prefer the method be quantitative. The registrant is encouraged to continue the HPLC method development that measures imidacloprid as imidacloprid and separately measures its major metabolites, and to present the Agency with the completed validated HPLC method and accompanying ILV data as soon as possible. CBTS

reiterates its observation that the registrant needs to keep the lab time of the HPLC method under 2 days as this is necessary for the method to be an effective enforcement procedure.

Method validation data for Bayer method 00200 from wheat and wheat processed commodities, barley, sorghum and sorghum processed commodities, and sugar beets and sugar beet processed commodities were presented. The preliminary method validation data for the cereal grains and sugar beets were generated from control samples of wheat forage, straw, and grain spiked individually with imidacloprid, its guanidine, olefin, hydroxy, and 6-CNA metabolites all at 0.1 ppm, then from a mixture of imidacloprid and the guanidine metabolite spiked into each control matrix at 0.1 ppm, 0.2 ppm, 1 ppm, 4 ppm, and 10 ppm. Recoveries of the individual compounds spiked at 0.1 ppm ranged from 81% in wheat forage to 103% in wheat straw. Recoveries of the mixture ranged from 88% from a 10 ppm spike in forage to 99% from a 4 ppm spiked in both grain and straw. The registrant has previously validated the method to 0.05 ppm for the rotational crops field trial data.

While the petitioner has validated the plant method at and above 0.1 ppm to gather the magnitude of the residue data from crop field trials, CBTS reiterates the LOQ of the method is 0.05 ppm and the MDL is at 0.01-0.02 ppm. CBTS reiterates the comments of our April 20, 1993, letter from R.A. Loranger that the petitioner needs to generate additional method validation data at the LOQ of 0.05 ppm on all commodities in this petition for which magnitude of the residue data are presented. CBTS suggests the petitioner use the protocol proposed and accepted in a co-pending petition to provide the necessary recovery data at the proposed tolerances which involves a triplicate recovery of a mixture composed of equal amounts of the parent, and its guanidine, hydroxy, olefin, and 6-CNA metabolites (each compound at 0.01 ppm) from each commodity. The use of one control sample with each set of recoveries is acceptable. With these additional recovery data at the LOQ of 0.05 ppm these new recovery data will also serve as the necessary method validation data for our suggested tolerances on barley grain, wheat grain, sorghum grain, sorghum forage, sorghum fodder, sugar beet root, and sugar beet tops.

Since the petitioner has not provided any method validation data at the proposed tolerances CBTS reiterates that these additional method validation data are required on barley and wheat forage and straw, and sugar beet molasses. Again CBTS suggests the petitioner use the protocol proposed and accepted in a co-pending petition to provide the necessary recovery data at the proposed tolerances on barley forage at 1.2 ppm, on barley straw at 0.2 ppm, wheat forage at 7 ppm, on wheat straw at 0.3 ppm, and on sugar beet molasses at 0.2 ppm which involves a triplicate recovery of a mixture composed of 1/2 parent plus 1/4 each of the guanidine and olefin metabolites from each of these commodities. The use of one control sample with each set of recoveries is acceptable.

Tolerance method validations (TMVs) were requested for Bayer methods 00191 (residues in milk and tissues) and 0200 (residues in plants) for imidacloprid and its metabolites in milk and liver, and

apples and cottonseed. The results of the successful method trials were reported by the Analytical Chemistry Branch. While ACB did not determine the methods' MDL (minimum detection limit) its estimate of 0.02 ppm in both methods is supported by chromatographic data. Based on acceptable recoveries with supporting chromatographic data there have been successful TMVs for Bayer methods 00200 and 00191. The methods are marginally suitable to be enforcement methods with perishable commodities as both the ILV and EPA time frame to complete a set of samples takes approximately 20 hours or into a third working day. CBTS reiterates these methods are quite rugged and effective as enforcement procedures when very rapid turn around times are not required. They meet all other requirements of Subdivision O and will be forwarded to FDA for publication in PAM, Vol II.

The registrant has presented ILV data for both methods. The ILV data for the plant method using apples were generated by Ricerca and the ILV data for the animal tissues method using liver were generated by Huntingdon Analytical Services. The ILV data are acceptable and are in agreement with the registrant's method validation data as well as the data generated by the Agency's method trials. The data support methods 00200 and 00191 as being capable of enforcing the proposed tolerances. There are supplementary ILV data for the residues in plants method at the LOQ.

STORAGE STABILITY

No new storage stability data were presented with this petition. The registrant has presented frozen storage stability data for imidacloprid and its metabolites in apples, potatoes, wheat matrices, cottonseeds, tomatoes, cauliflower, and lettuce. Frozen storage at -20°C stability data were presented for various time intervals up to 24 months. Frozen storage stability data were also generated and reported using ^{14}C-imidacloprid in lemons, corn, and lettuce for various time intervals to 24 months. These studies have been previously reviewed in PP#s 3F4169 and 3F4231 (see memoranda by F. Griffith dated Sept. 21, 1993 and June 22, 1994).

Imidacloprid and its metabolites are stable in potatoes, apples, apple juice, and pomace; cottonseed, cottonseed hulls, soapstock, and oil as well as wheat grain, forage, and straw, and in wheat processed commodities at -20°C for at least 18-20 months. There are supplementary storage stability data that show imidacloprid and its metabolites both labeled and unlabeled are stable in lettuce under conditions of frozen storage for at least 24 months. These data are sufficient to support the magnitude of the residue crop field trial data for wheat, barley, sorghum, and sugar beets.

MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALS

BARLEY (MRID #s 431592-01 and 431592-07)

The petitioner presented imidacloprid magnitude of the residue data in barley in a study titled "Determination of Imidacloprid Residues in Winter Barley" by S. Shen dated January 3, 1994, coded Gustafson Project number 92912 and ABC Laboratories study number

40545. The petitioner also presented additional magnitude of the residue data on barley in a study titled "Imidacloprid (240FS) - Magnitude of the Residue on Seed Treated Barley" by C. Lenz dated December 2, 1992, and coded Miles report number 103916.

The petitioner presented total imidacloprid magnitude of the residue data on barley from 7 field trials in Minnesota, Idaho, California, Indiana, Nebraska, Washington, and Kansas all from the 1991 crop year on 4 varieties. The petitioner also presented total imidacloprid magnitude of the residue data on barley from 2 states in Oregon and New York from the 1993 crop year on 2 additional varieties. Based on the EPA guidance on number and location of domestic crop field trials published in June 1994 for the establishment of tolerance we now need 12 field trials and 24 samples for barley. The petitioner needs to present additional magnitude of the imidacloprid residue data on barley from 4 additional trials as follows; one trial from Region 5, 2 trials from Region 7, and 1 trial from Region 9. Regions are defined in the June 1994 document "EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances." Crop field trial data from these 9 states represents 2,343,000 acres of barley harvested out of a national barley production harvested from 7,499,000 acres (31.2%) [see 1991 Agr. Stat.].

The 1991 barley field trials were conducted using seed treated with the Gaucho 240 FS formulation at a rate of 2 oz or 0.125 lb a.i. imidacloprid/100 lbs of seed. The petitioner needs to provide the barley seeding rate per acre so that we will be able to determine the rate of imidacloprid applied per acre for all of the 1991 barley field trials. The 1993 barley field trials were conducted with both Gaucho 240 FS and Gaucho 480F at a rate of 2 ozs or 0.125 lb ai imidacloprid per 100 lbs of seed. The 1993 barley seeding rate per acre ranged from 73 lbs (1.5 bushels)/acre in Oregon to 160 lbs (3.3 bushels)/acre in New York. The rate of imidacloprid application to the soil from treated seed ranged from 0.09 lb ai to 0.2 lb ai/A. A separate control test plot was planted and harvested at each test site.

Barley forage samples were gathered at earliest grazing or 4-6" which varied from 34 to 85 days after planting (PHI) in 1991 and at 45 days in 1993. Barley grain and straw were harvested at earliest maturity which varied from 95 to 195 days (PHI) in 1991 and from 292 to 301 days in 1993. Control and treated samples were collected from 12 separate areas of each test plot. The barley forage, grain, and straw were frozen following harvest and remained frozen until sample processing and analysis. The 1993 barley samples remained in frozen storage from harvest to analysis a period of 2 months and the 1991 barley commodity samples were stored a maximum of 16 months. There are adequate storage stability data to support the magnitude of the imidacloprid residue data on barley.

The barley forage, grain, and straw samples were analyzed by the residue analytical method reviewed above. Adequate method validation and concurrent recovery data have been presented to support the gathering of the magnitude of the imidacloprid residue data from barley grain forage, grain, and straw for all samples at and above 0.1 ppm. Concurrent recoveries of a mixture of imidacloprid and its

guanidine metabolite spiked at 0.1, 0.2/0.4, and 1 ppm into control barley grain ranged from 81% to 94%, and into barley straw ranged from 76% to 111%. The petitioner has supplied adequate raw data, including copies of supporting chromatograms from the 1991 samples to show that the LOQ is <0.05 ppm and the MDL is 0.01 ppm. The petitioner did not provide adequate raw data, including an adequate number of copies of supporting chromatograms, for the 1993 imidacloprid barley crop field trial data. The petitioner needs to revise the 1993 report to have the LOQ at <0.05 ppm and the MDL at 0.01-0.02 ppm for all samples of barley forage, grain, and straw. The petitioner is reminded that CBTS sets tolerances no higher than necessary. The raw data needed from the 1993 report is the chromatographic counts for each sample and a copy of each chromatogram not already submitted as we feel from our review of the few chromatograms submitted that there are real residues of total imidacloprid present in treated barley straw ranging from 0.02 ppm to 0.1 ppm. The raw data and copies of supporting chromatograms are needed so that we can independently verify the reported results.

No barley hay samples were harvested and analyzed for total imidacloprid residues. For the 1991 and 1993 field trials we will not require barley hay residue data and will use a concentration factor of 2.93 to determine residues in barley hay from barley forage. For the 4 new imidacloprid barley field trials the petitioner will need to present residue data for barley hay in additional to residue data from barley grain, forage, and straw. The petitioner will need to present along with the imidacloprid residue data on barley hay the percent moisture for each barley hay sample.

For the 1991 control barley grain, forage, and straw samples no imidacloprid residues were detected to the LOQ of <0.05 ppm. Total imidacloprid residues in the 1991 barley forage ranged from 0.03 ppm to 1.09 ppm with 1 sample having residues above 0.5 ppm. Using the 2.93 dry down factor, imidacloprid residues in barley hay would ranged from 0.09 ppm to 3.2 ppm. Total imidacloprid residues in the 1991 barley grain ranged from < 0.01 ppm to 0.04 ppm with 6 grain samples having 0.01 ppm and above residues. The 1991 barley straw had total imidacloprid residues ranging from 0.05 ppm to 0.2 ppm with 2 samples having residues above 0.1 ppm.

For the 1993 control barley grain, forage, and straw samples no imidacloprid residues were detected to the "LOQ" of <0.1 ppm. No imidacloprid residues in barley grain were reported at and above 0.1 ppm. Total imidacloprid residues on winter barley forage were from Oregon only and ranged from 0.1 ppm to 0.23 ppm. Using the 2.93 ppm dry down factor imidacloprid residues in barley hay from the 1993 crop year could range from 0.29 ppm to 0.67 ppm. Due to adverse weather conditions a good sample of barley forage could not be harvested from the New York field trial. The barley straw from the 1993 crop year had total imidacloprid residues ranging all <0.1 ppm.

CBTS declines to accept the 1993 imidacloprid barley crop field trial data as adequate to support the proposed imidacloprid tolerances on barley grain, forage, and straw until we have reviewed the revised crop field trial report. The petitioner is reminded that we set

tolerances no higher than necessary. Thus, the petitioner may have to propose in a revised Section F a tolerance for barley grain at 0.05 ppm. The petitioner will need to propose a total imidacloprid tolerance on barley hay once all of the crop field trial data are gathered. Judgement is deferred on the adequacy to the proposed imidacloprid tolerances at 0.1 ppm on barley grain, 0.2 ppm on barley straw, and 1.2 ppm on barley forage until we have reviewed the revised 1993 crop field trial report and the additional magnitude of the residue crop field trial data needed.

WHEAT (MRID #s 431756-01 and 431592-02)

The petitioner presented imidacloprid magnitude of the residue data in wheat in a study titled "Determination of Imidacloprid Residues in Winter Wheat" by S.Shen dated January 3, 1994, and coded Gustafson project numbers 92911, 92913, and 93815, and ABC Laboratories study number 40646. The petitioner also presented additional magnitude of the residue data on wheat in a study titled "Imidacloprid (240FS) - Magnitude of the Residue on Seed Treated Wheat" by C. Lenz dated December 2, 1992, and coded Miles report number 103934.

The petitioner presented total imidacloprid magnitude of the residue data on wheat from 6 field trials in Minnesota, Idaho, California, Indiana, Nebraska, and Kansas all from the 1991 crop year on 4 varieties. The petitioner also presented total imidacloprid magnitude of the residue data from 10 states in Georgia, Kansas, Minnesota, Mississippi, Montana, Nebraska, Oregon, New York, Ohio, and Oklahoma all from the 1993 crop year on 6 varieties. Based on the EPA guidance on number and location of domestic crop field trials for the establishment of tolerance we now need 20 field trials and 40 samples for wheat. The petitioner needs to present additional magnitude of the imidacloprid residue data on wheat from 6 additional trials as follows; one trial from Region 5, 2 trials from Region 7, and 3 trials from Region 8. Crop field trial data from these 13 states represents 34,927,000 acres of wheat harvested out of a national wheat production harvested from 69,353,000 acres (50.4%) [see 1991 Agr. Stat.].

The 1991 wheat field trials were conducted using seed treated with the Gaucho 240FS formulation at a rate of 2 oz or 0.125 lb a.i. imidacloprid/100 lbs of seed. The petitioner needs to provide the wheat seeding rate per acre so that we will be able to determine the rate of imidacloprid applied per acre for all of the 1991 wheat field trials. The 1993 wheat field trials were conducted with both Gaucho 240 FS and Gaucho 480F at a rate of 2 ozs or 0.125 lb ai imidacloprid per 100 lbs of seed. The 1993 wheat seeding rate per acre ranged from 80 lbs (1.33 bushels)/acre in Oklahoma to 198 lbs (3+ bushels)/acre in New York. The rate of imidacloprid application to the soil from treated seed ranged from 0.1 lb ai to 0.225 lb ai. A separate control test plot was planted and harvested at each test site.

Wheat forage samples were gathered at earliest grazing or 4-6" which varied from 35 to 59 days after planting (PHI) in 1991 and from 57 to 231 days in 1993. Wheat grain and straw were harvested at earliest maturity which varied from 95 to 223 days (PHI) in 1991 and from 205 to 319 days in 1993. Control and treated samples were

collected from 12 separate areas of each test plot. The wheat forage, grain, and straw were frozen following harvest and remained frozen until sample processing and analysis. The 1993 wheat samples remained in frozen storage from harvest to analysis a period of 5+ months and the 1991 wheat commodity samples were stored a maximum of 14 months. There are adequate storage stability data to support the magnitude of the imidacloprid residue data on wheat.

The wheat forage, grain, and straw samples were analyzed by the residue analytical method reviewed above. Adequate method validation and concurrent recovery data have been presented to support the gathering of the magnitude of the imidacloprid residue data from wheat grain forage, grain, and straw for all samples at and above 0.1 ppm. Concurrent recoveries of a mixture of imidacloprid and its guanidine metabolite spiked at 0.1, 0.2, and 1 ppm into control wheat grain ranged from 78% to 113%, and into wheat straw ranged from 75% to 119%. The petitioner has supplied adequate raw data, including copies of supporting chromatograms from the 1991 samples to show that the LOQ is <0.05 ppm and the MDL is 0.01 ppm. The petitioner did not provide adequate raw data, including an adequate number of copies of supporting chromatograms, for the 1993 imidacloprid wheat crop field trial data. The petitioner needs to revise the 1993 report to have the LOQ at <0.05 ppm and the MDL at 0.01-0.02 ppm for all samples of wheat forage, grain, and straw. CBTS reiterates that we set tolerances no higher than necessary. The raw data needed from the 1993 report is the chromatographic counts for each sample and a copy of each chromatogram not already submitted as we feel from our review of the chromatograms submitted that there are real residues of total imidacloprid present in treated wheat forage and straw ranging from 0.02 ppm to 0.1 ppm. The raw data and copies of supporting chromatograms are needed so that we can independently verify the reported results.

No wheat hay samples were harvested and analyzed for total imidacloprid residues. For the 1991 and 1993 field trials we will not require wheat hay residue data and will use a concentration factor of 3.52 to determine residues in wheat hay from wheat forage. For the 6 new imidacloprid wheat field trials the petitioner will need to present residue data for wheat hay in additional to residue data from wheat grain, forage, and straw. The petitioner will need to present along with the imidacloprid residue data on wheat hay the percent moisture for each wheat hay sample.

For the 1991 control wheat grain, forage, and straw samples no imidacloprid residues were detected to the LOQ of <0.05 ppm. Total imidacloprid residues in the 1991 wheat forage ranged from 0.09 ppm to 4.52 ppm with 2 samples having residues above 0.5 ppm. Using the 3.52 dry down factor imidacloprid residues in wheat hay would range from 0.32 ppm to 15.9 ppm. Total imidacloprid residues in the 1991 wheat grain ranged from < 0.01 ppm to 0.04 ppm with 4 grain samples having 0.01 ppm residues. The 1991 wheat straw had total imidacloprid residues ranging from 0.05 ppm to 0.22 ppm with 3 samples having residues above 0.1 ppm.

For the 1993 control wheat grain, forage, and straw samples no imidacloprid residues were detected to the "LOQ" of <0.1 ppm. No

imidacloprid residues in wheat grain were reported at and above 0.1 ppm. Total imidacloprid residues on winter wheat forage ranged from <0.1 ppm to 6.82 ppm with 12 samples having residues above 0.5 ppm. Using the 3.52 ppm dry down factor imidacloprid residues in wheat hay from the 1993 crop year could range from 0.35 ppm to 24 ppm. The wheat straw from the 1993 crop year had total imidacloprid residues ranging from <0.1 ppm to 0.3 ppm with 4 samples of straw having residues above 0.2 ppm.

CBTS declines to accept the 1993 imidacloprid wheat crop field trial data as adequate to support the proposed imidacloprid tolerances on wheat grain, forage, and straw until we have reviewed the revised crop file trial report. The petitioner is reminded that we set tolerances no higher than necessary. Thus, the petitioner may have to propose in a revised Section F a tolerance for wheat grain at 0.05 ppm. The petitioner will need to propose a total imidacloprid tolerance on wheat hay once all of the crop field trial data are gathered. Judgement is deferred on the adequacy to the proposed imidacloprid tolerances at 0.1 ppm on wheat grain, 0.3 ppm on wheat straw, and 7 ppm on wheat forage until we have reviewed the revised 1993 crop field trial report and the additional magnitude of the residue crop field trial data needed.

Total imidacloprid residues on aspirated wheat grain fractions were not presented. However, since the proposed use is a seed treatment as opposed to a late season foliar or post harvest application CBTS will not require any imidacloprid residue data at this time for aspirated wheat grain fractions. The petitioner/registrant is reminded that if there are additional uses proposed at a later date for either foliar application or post harvest application to wheat, then total imidacloprid residue data on aspirated grain fractions will need to be provided.

SORGHUM (MRID # 431592-05)

The petitioner presented imidacloprid magnitude of the residue data in grain sorghum in a study titled "Determination of Imidacloprid Residues in Sorghum" by S. Shen dated February 14, 1994, and coded Gustafson project number 93211 and ABC Laboratories study number 40957.

The petitioner presented total imidacloprid magnitude of the residue data on grain sorghum from 12 field trials in Arkansas, California, Colorado, Louisiana, Missouri, North Carolina, Nebraska, Kansas (2), South Dakota, and Texas (2) all from the 1993 crop year on 3 varieties. Based on the EPA guidance on number and location of domestic crop field trials for the establishment of tolerance we now need 12 field trials and 24 samples for grain sorghum from specified locations. The petitioner needs to present additional magnitude of the imidacloprid residue data on grain sorghum from 3 additional trials as follows; 2 trials from Region 5, and 1 trial from Region 8. Crop field trial data from these 10 states represents 8,243,000 acres of grain sorghum harvested out of a national grain sorghum production harvested from 9,079,000 acres (90.8%) [see 1991 Agr. Stat.].

The 1993 grain sorghum field trials were conducted using seed treated with the Gaucho 480 F formulation at a rate of 8 oz or 0.5 lb a.i. imidacloprid/100lbs of seed and on a separate test plot using seed treated with Gaucho 480 F at a rate of 4 oz or 0.25 lb ai imidacloprid/100 lbs seed plus overtreated at planting with Gaucho® 70% HB at a rate of 4 oz or 0.25 lb ai imidacloprid/100 lbs seed. The 1993 grain sorghum seeding rate per acre ranged from 5.1 lbs/acre in South Dakota to 34 lbs/acre in California. The rate of imidacloprid application to the soil from treated seed ranged from 0.1 oz (0.0063 lb) ai to 0.68 oz (0.0425 lb) ai. A separate control test plot was planted and harvested at each test site.

Grain sorghum forage samples were gathered at the milk stage; ie, forage with grain heads which varied from 65 to 125 days after planting (PHI) in 1993. Sorghum grain and fodder were harvested at earliest maturity which varied from 96 to 143 days (PHI) in 1993. At maturity the grain was thrashed from the plant. Control and treated samples were collected from 12 random (separate) areas of each test plot. The sorghum forage, grain, and fodder were frozen following harvest and remained frozen until sample processing and analysis. The sorghum samples remained in frozen storage from harvest to analysis for a period of 3-4 months. There are adequate storage stability data to support the magnitude of the imidacloprid residue data on grain sorghum.

The sorghum forage, grain, and straw samples were analyzed by the residue analytical method reviewed above. Adequate method validation and concurrent recovery data have been presented to support the gathering of the magnitude of the imidacloprid residue data from sorghum grain forage, grain, and straw for all samples at and above 0.1 ppm. Concurrent recoveries of a mixture of imidacloprid and its guanidine metabolite spiked at 0.1, 0.2, and 1 ppm into control sorghum forage ranged from 76% to 101%, and into sorghum grain ranged from 82% to 89%. The petitioner did not provide adequate raw data, including an adequate number of copies of supporting chromatograms, for the 1993 imidacloprid sorghum crop field trial data. The petitioner needs to revise the 1993 report to have the LOQ at <0.05 ppm and the MDL at 0.01-0.02 ppm for all samples of sorghum forage, grain, and straw. CBTS reiterates that we set tolerances no higher than necessary. The raw data needed from the 1993 report is the chromatographic counts for each sample and a copy of each chromatogram not already submitted as we feel from our review of the chromatograms submitted that there are real residues of total imidacloprid present in treated sorghum forage, grain, and fodder ranging from 0.02 ppm to 0.1 ppm. The raw data and copies of supporting chromatograms are needed so that we can independently verify the reported results.

For the 1993 control sorghum grain, forage, and straw samples no imidacloprid residues were detected to the "LOQ" of <0.1 ppm. Total imidacloprid residues in the sorghum forage ranged from <0.1 ppm to 0.1 ppm on 1 sample. Total imidacloprid residues in the 1993 sorghum grain and fodder were all < 0.1 ppm.

CBTS declines to accept the 1993 imidacloprid sorghum crop field trial data as adequate to support the proposed imidacloprid tolerances

on sorghum grain, forage, and fodder until we have reviewed the revised crop field trial report. The petitioner is reminded that we set tolerances no higher than necessary. Thus, the petitioner may have to propose in a revised Section F a tolerance for sorghum grain at 0.05 ppm. Judgement is deferred on the adequacy to the proposed imidacloprid tolerances at 0.1 ppm on sorghum grain, forage, and fodder until we have reviewed the revised 1993 crop field trial report and the additional magnitude of the residue crop field trial data needed. In the revised report the petitioner should clearly label which data were generated from the use of Gaucho® 70 HB and which were generated from use of Gaucho® 480 F only.

Total imidacloprid residues on aspirated sorghum grain fractions were not presented. However, since the proposed use is a seed treatment as opposed to a late season foliar or post harvest application CBTS will not require any imidacloprid residue data at this time for aspirated sorghum grain fractions. The petitioner/registrant is reminded that if there are additional uses proposed at a later date for either foliar application or post harvest application to sorghum, then total imidacloprid residue data on aspirated grain fractions will need to be provided.

COMMENTARY ON SMALL GRAINS

CBTS is aware that a question will arise as to why there are differences in residue values and the proposed tolerances between the forages of the representative commodities sorghum and wheat. This is expected as the rate of seeding, thus the application rate of imidacloprid to the soil is quite different. In the wheat field trials the rate of wheat seeding leads to a 5-6X higher imidacloprid application to soil; eg, up to 0.225 ai imidacloprid from seeding treated wheat vs. up to 0.04 ai imidacloprid from seeding treated sorghum. The differences between 7 ppm for wheat forage and 0.1 ppm for sorghum forage can further be explained by size of the plants with sorghum plants being significantly larger than wheat. Therefore, the applied imidacloprid is further diluted within the green forage.

SUGAR BEETS (MRID # 431592-03)

The petitioner presented imidacloprid magnitude of the residue data in sugar beet tops and roots in a study titled "Determination of Imidacloprid Residues in Sugar Beets" by S. Shen dated February 4, 1994, and coded Gustafson project number 93214 and ABC Laboratories Study number 40968.

The petitioner presented total imidacloprid magnitude of the residue data on sugarbeet tops and roots from 8 field trials in California, Idaho, Michigan, Minnesota, North Dakota, Nebraska, Wyoming, and Texas all from the 1993 crop year on 6 varieties. Based on the EPA guidance on number and location of domestic crop field trials for the establishment of tolerance we now need 12 field trials and 24 samples for sugarbeet tops and roots from specified locations. The petitioner needs to present additional magnitude of the imidacloprid residue data on sugarbeet tops and roots from 4 additional trials as follows: 2 trials from Region 5, 1 trial from Region 10, and 1 trial

from Region 11. Crop field trial data from these 8 states represents 1,244,000 acres of sugarbeets harvested out of a national sugarbeet production harvested from 1,377,500 acres (90.3%) [see 1991 Agr. Stat.].

The 1993 sugarbeet field trials were conducted using seed treated with the Gaucho 75 WP formulation at a rate of 12 lbs or 9 lbs a.i. imidacloprid/100 lbs of seed. The 1993 sugarbeet seeding rate per acre ranged from 1.7 lbs/acre in North Dakota to 10.7 lbs/acre in California. The rate of imidacloprid application to the soil from treated seed ranged from 0.15 lb ai/acre to 0.96 lb ai/acre. A separate control test plot was planted and harvested at each test site.

Sugarbeet tops and roots samples were gathered at maturity which varied from 128 to 181 days (PHI) in 1993. At maturity the roots with the tops attached were harvested. Control samples and the treated samples were collected from 12 random (separate) areas of each test plot. The sugarbeet tops from all 12 plants were saved as the forage sample. The adhering soil on the roots was removed by brushing with soft vegetable brushes. The sugarbeet roots were cut into quarters and opposite quarters were gathered as the root sample. Samples were frozen following harvest and remained frozen until sample processing and analysis. The sugarbeet samples remained in frozen storage from harvest to analysis for less then 34 days. There are adequate storage stability data to support the magnitude of the imidacloprid residue data on sugarbeet tops and roots.

The sugarbeet tops and roots samples were analyzed by the residue analytical method reviewed above. Adequate method validation and concurrent recovery data have been presented to support the gathering of the magnitude of the imidacloprid residue data from sugarbeet roots and tops for all samples at and above 0.1 ppm. The petitioner did not provide adequate raw data for the 1993 imidacloprid sugarbeet crop field trial data. Concurrent recoveries of a mixture of imidacloprid and its guanidine metabolite spiked at 0.1, 0.2, and 1 ppm into control sugar beet tops ranged from 78% to 107%, and into sugarbeet roots ranged from 82% to 104%. The petitioner provided adequate supporting chromatographic data for this study to allow independent verification of the results. The petitioner claims a 0.1 ppm LOQ; however, review of the supporting chromatographic data confirm a 0.05 ppm LOQ and a 0.01-02 ppm MDL for both sugarbeet tops and roots. UARs are not a problem in either of the rac sugarbeet tops and roots samples.

The petitioner needs to revise the 1993 report to have the LOQ at <0.05 ppm and the MDL at 0.01-0.02 ppm for all samples of sugarbeet tops and roots. CBTS reiterates that we set tolerances no higher than necessary and a LOQ of 0.05 ppm and a MDL of 0.01 ppm would be consistent with the values generated for other commodities. The raw data needed from the 1993 report is the chromatographic counts for each sample. We feel from our review of the chromatograms submitted that there are real residues of total imidacloprid present in treated sugarbeet tops and roots ranging from 0.02 ppm to 0.1 ppm. The raw

data along with copies of supporting chromatograms are needed so that we can independently verify the reported results.

For the 1993 control sugarbeet tops and roots samples no imidacloprid residues were detected to the "LOQ" of <0.1 ppm. Total imidacloprid residues in the sugarbeet forage/tops were all <0.1 ppm; however, review of the chromatograms indicates residues were present between <0.02 ppm (1 sample) to approximately 0.1 ppm. Total imidacloprid residues in the 1993 sugarbeet roots were all < 0.1 ppm; however, review of the chromatograms indicates residues were present between <0.02 ppm (2 samples) to approximately 0.05 ppm.

CBTS declines to accept the 1993 imidacloprid sugarbeet crop field trial data as adequate to support the proposed imidacloprid tolerances on sugarbeet tops and roots at 0.1 ppm until we have reviewed the revised crop field trial report. The petitioner is reminded that we set tolerances no higher than necessary. Thus, the petitioner may have to propose in a revised Section F a tolerance for sugarbeet roots at 0.05 ppm. Judgement is deferred on the adequacy of the proposed imidacloprid tolerances at 0.1 ppm on sugarbeet tops and roots until we have reviewed the revised 1993 crop field trial report and the additional magnitude of the residue crop field trial data needed.

ROTATIONAL CROPS - FIELD ACCUMULATION STUDIES

No new rotational crops field accumulation studies were presented in this petition.

Previously, the registrant has presented adequate limited field rotational crop studies from 3 sites; ie, California, Mississippi, and Kansas with an in-furrow soil application of the 2.5% granular formulation at a rate of 0.29 to 0.32 lbs ai imidacloprid and soil aged 1, 4, 8, and 11 months before replanting with the cereal grains wheat or sorghum, turnips as the root crop, and mustard greens or spinach as the leafy vegetable. After the plots were treated with imidacloprid the registrant planted them with a cover crop and maintained the crop until the proper replant interval at which time the cover crop was plowed under.

The registrant planted adjacent untreated control plots at each test site. The control samples were planted, harvested, and handled in the same manner as the test samples. All rotational crops were harvested at maturity with additional samples of immature sorghum and wheat being collected at 45 days after planting.

Total imidacloprid residues were at or about the minimum detection limit (MDL) of 0.01 ppm by 11 months. CBTS would not expect total imidacloprid residues to be present after 12 months in cereal or small grains, root crops, or leafy vegetables. These limited field crop rotational studies with the 3 crop groups support an overall 12 month plant back restriction for no detectable residues to be present in rotated crops and that no rotational crop imidacloprid tolerances are necessary with such a restriction.

MAGNITUDE OF THE RESIDUES - PROCESSED FOOD/FEED

WHEAT (MRID # 431756-02)

The petitioner presented magnitude of the residue data in wheat processed commodities in a study titled "Imidacloprid (240FS) - Magnitude of the Residue on Wheat Processed Products" by A. Maloney dated June 7, 1993, and coded Miles report number 105007.

One additional wheat field trial was conducted in Indiana during the 1991 crop year using the Butte variety. The seeds were treated with Gaucho® 240 FS at a rate of 0.625 lb a.i. imidacloprid per 100 lbs of seed (5X exaggerated application rate). The treated wheat seeds were planted on March 21. However, the seeding rate per acre was not specified; thus, CBTS cannot determine the imidacloprid application rate/acre. The petitioner needs to provide the seeding rate. The mature wheat grain was harvested on July 9, 1991, for a 110 day PHI. A control plot was also planted at the same test site. Approximately 50 pounds of control wheat sample was harvested before harvesting approximately 50 lbs of the treated wheat grain. The rac wheat was shipped unfrozen to the processor and stored frozen until August 15 when processing started. After completing the processing on August 26, 1991, the rac wheat and processed wheat fractions were frozen and returned to Miles before being sent on June 4, 1992, to ABC Laboratories for analysis.

The rac wheat, and the processed wheat fractions bran, flour, shorts, and middlings samples were analyzed 19 months after harvest using the plant residue method reviewed above. The petitioner provided adequate concurrent validation data to show the method can gather magnitude of the residue data for the rac wheat, and the processed commodities generated during the processing study. Recoveries of a mixture of imidacloprid and its guanidine metabolite spiked into control wheat, bran, flour, and middlings at 0.1, 0.5, and 2 ppm ranged from 72% to 99%. The petitioner provided for this study adequate supporting chromatographic data with the counts for each peak to allow independent verification of the results. The petitioner claims a 0.1 ppm LOQ; however, review the supporting chromatographic data confirms a 0.05 ppm LOQ and a 0.01-02 ppm MDL for wheat and the wheat processed commodities. UARs, while present, are not a problem in the rac wheat, bran, flour, and middlings samples.

The processing done by the Food Protein R&D Center at Texas A&M University simulated commercial wheat processing and was a material balance study. Starting with 47 lbs of raw wheat the wheat was dried to a moisture content of 11.2%, then the wheat is aspirated and screened (3/16") to produce 45.2 lbs of cleaned seed/grain, 0.6 lb of light impurities, and around 7 grams of small screenings. The grain was conditioned by addition of water to have a 16% moisture content. The tempering was for 12 hours 20 minutes. The milling process consisted of 4 break and reduction steps using Allis-Chalmers corrugated and smooth roller mills. After each of the 4 breaks, the samples were sieved with a Great Western Sample-Sifter using sieve sizes of 730, 390,, 240, and 132 microns. The fraction on top of the 730 micron sieve after the fourth break is the 6.9 lbs of bran. The

fractions on top of the 390 and 240 sieve are combined and weighed to produce the 33.5 lbs of middlings.

The middlings are reduced four times through the smooth roller mill and sieved after each reduction. The material on top of the 390, 240, and 132 are combined and reduced/rolled again. After the fourth reduction and seining the material on top of the 390 and 240 micron sieves is combined and weighed to produce 9.7 lbs of shorts. All of the material on top of the 132 micron sieve from both the break and reduction steps is combined to produce 16.3 lbs of low grade flour. All of the material that passes through the 132 micron sieve is 8.9 lbs of patent flour.

No total imidacloprid residues were detected in any of the control and treated rac wheat grain to the "LOQ" of 0.1 ppm. However, review of the supporting chromatograms indicates there are total imidacloprid residues in the rac treated wheat grain near 0.02 ppm. When this wheat was processed into bran, middlings, shorts, and flour the residues in the middlings were near the MDL of 0.01 ppm, thus no FAT is necessary for middlings. 0.07 ppm total imidacloprid was detected in bran which indicates a concentration factor near 3.5X, and a FAT will probably be necessary. Total imidacloprid residues were detected in the flour near 0.015 ppm and at 0.02 ppm in shorts. The petitioner will need to recalculate all total imidacloprid residues at and above the MDL so that we can determine the proper concentration/decline factor for each wheat processed commodity.

The petitioner has conducted an adequate wheat processing study using wheat bearing detectable residues following an exaggerated 5X imidacloprid application to the seeds. However, the petitioner needs to present a revised final report recalculating the results based on a 0.05 ppm LOQ and a 0.01-0.02 ppm MDL as well as provide data on the seeding rate. Judgement is deferred on the results of this imidacloprid wheat processing study until we have received information on the seeding rate, reviewed the recalculated results and the petitioner's revised conclusions. CBTS expects that real residues of total imidacloprid in bran will require a FAT and the residues in the shorts and possibly the flour may require a FAT. CBTS points out that we may not require tolerances on these processed commodities; ie, shorts and flour, if there is a small concentration factor and we are dealing with low level residues as we do not consider this to be a real concentration due to possible sample variations and/or to the residue analytical method's ability to accurately distinguish between numbers.

BARLEY

The petitioner did not present a barley processing study. As long as the petitioner has presented valid processing studies for the representative commodity wheat CBTS will not require an additional processing study for barley.

CBTS reminds the petitioner that if barley is separated from the representative commodities wheat and sorghum by revised Sections B and F, then a separate barley processing study will be necessary. Likewise, if the registrant/petitioner at a later date proposes foliar

applications for barley and significant total imidacloprid residues are found on the barley grain, then CBTS will reassess the need for a barley processing study. CBTS points of that in Table II (June 1994) the processing commodities are different for barley and wheat.

SORGHUM (MRID # 431592-06)

The petitioner presented magnitude of the residue data from a sorghum processing study in a document titled " Determination of Imidacloprid Residue in Processed Sorghum Fractions" by S. Shen dated February 3, 1994, and coded Gustafson project number 933B9 and ABC Laboratories study number 40967.

One additional sorghum field trial was conducted in Texas during the 1993 crop year using the Cargill 837 variety of seed. The seed were treated with Gaucho® 480 F at a rate of 1 quart or 1 lb a.i. imidacloprid per 100 lbs of seed (2X exaggerated application rate). The treated sorghum seed were planted at a rate of 7 lbs/acre on April 5 for an application rate of 0.07 lb a.i imidacloprid/acre. The mature grain was harvested on July 21 for a 107 day PHI. A control plot was also planted at the same test site and the control sorghum grain samples were harvested before the treated grain samples. The moisture of the sorghum grains was approximately 12%. Samples were placed on dry ice and remained frozen at -20°C until sample preparation and analysis. One set of control and treated rac sorghum grains arrived at ABC Laboratories unfrozen but cold. The set was replaced with a frozen set of sorghum grain samples.

Sorghum grain samples were analyzed 3 months after harvest using the plant residue method reviewed above. The petitioner provided adequate method and concurrent validation data to show the method can gather magnitude of the residue data for the rac in the sorghum processing study. Recoveries of a mixture of imidacloprid and its guanidine metabolite spiked into control sorghum grain at 0.05 ppm and 0.1 ppm ranged from 82% to 99%. The petitioner provided adequate supporting chromatographic data for this study to allow independent verification of the results. The petitioner claims a 0.1 ppm LOQ; however, review the supporting chromatographic data confirm a 0.05 ppm LOQ and a 0.01-02 ppm MDL for the sorghum grain for the processing study. UARs are not a problem in the rac sorghum grain samples.

No total imidacloprid residues were detected in any of the control and treated sorghum grain samples to the LOQ of 0.1 ppm. Review of the treated sample chromatograms confirm that there are no total imidacloprid residue to a LOQ of 0.05 ppm, but there are detectable total imidacloprid residues near the MDL of 0.01 ppm.

The petitioner claims that since there are no detectable total imidacloprid residues at or above the LOQ (of 0.05 ppm) in the rac sorghum grain from an exaggerated 2X seed treatment application of Gaucho then a sorghum processing study is not required. CBTS reiterate our comments of the April 20, 1993, letter where we agreed with the petitioner's conclusion. CBTS also points out that in Table II (June 1994) sorghum flour is listed as the only processed commodity from grain sorghum and we are not requiring residue data on this

sorghum flour at this time, thus a sorghum processing study is not required.

SUGARBEETS (MRID # 431592-04)

The petitioner presented magnitude of the residue data in sugar beets processing fractions in a study titled " Determination of Imidacloprid Residues in Processed Sugar Beet Fractions" by S. Shen dated February 15, 1994, and coded Gustafson project number 93212 and ABC Laboratories study number 40969.

One additional sugarbeet field trial was conducted in California during the 1993 crop year using the Hill 2 variety. The seeds were treated with Gaucho® 75 WP at a rate of 24.1 lbs a.i. imidacloprid per 100 lbs of raw seed (2.68X exaggerated application rate). The treated sugarbeet seeds were planted at a rate of 7.5 lbs/acre on April 30 for an application rate of 1.8 lbs a.i imidacloprid/acre. The mature sugarbeet roots were harvested on October 22 for a 175 day PHI. A control plot was also planted at the same test site. Approximately 350 pounds of control sugarbeet root samples were harvested before harvesting approximately 350 lbs of the treated sugarbeet roots. Samples were frozen until sample processing, then were refrozen after processing into the various fractions until sample preparation and analysis. The frozen rac sugarbeets were shipped to the processor and stored frozen until November 9 when processing started. After completing the processing on November 15 the rac and processed fractions were shipped to ABC Laboratories for analysis.

The processing done by Wm. J. Englar & Assoc. simulated commercial sugarbeet processing and was a material balance study. Starting with 223.3 lbs of raw sugarbeets the beets were washed to remove the soil and trash before being sliced in a LanElec Vegetable Slicer to produce the 190 lbs of cossettes 1-3 mm thick. Cossettes then proceeded to the diffusion step. In this small scale processing cossette diffusion is countercurrent with the cossettes in stainless steel baskets being moved from cell to cell and the diffusion liquid being moved from cell to cell in the opposite direction. The diffusion was for 60-70 minutes at 70-75°C. After diffusion 234 lbs of thin juice was available for purification. The wet beet pulp was pressed using a Suntech Fruit Press and 71.2 lbs of thin juice was added back to the diffuser. No sample of wet beet pulp was gathered for analysis. The wet beet pulp was dried to less then 10% moisture using a lab bin air dryer to produce 5.2 lbs of dried beet pulp. The dried beet pulp was gathered and frozen for analysis.

The raw juice of 10-15% Brix is purified by the addition of lime and CO_2 to maintain a pH near 10 for 20 minutes at 80°C. In the lab the thin juice was allowed to settle and the supernatant liquor was decanted, then the sludge was filtered. The thin juice was carbonated again at 90-95°C for 5-15 minutes with the pH near 8.1-8.5, then filtered. 206.5 lbs of thin juice is concentrated in a Groen Steam Vacuum Pan maintained at 18" Hg to produce 28.2 lbs of thick juice. The thick juice Brix is increased by adding lower grade sugars (seed crystals) to form the standard liquor. In the lab the 21.1 lbs of standard liquor is boiled to the massecuite in a small laboratory

vacuum pan. The 13.7 lbs massecuite is centrifuged to obtain sugar from the mother liquor. The sugar is washed with hot clear water at 95°C, then centrifuged. The initial spin off is 4.5 lbs of molasses. The wet sugar is dried to 3 lbs of fine sugar in the lab using a Kitchen Aid Mixer with warm air against the side to promote drying. Mixing prevent agglomeration.

The rac sugarbeets, and the processed fractions molasses, fine sugar, and dried pulp samples were analyzed 1 month after harvest using the plant residue method reviewed above. The petitioner provided adequate method and concurrent validation data to show the method can gather magnitude of the residue data for the rac sugarbeets, and the processed commodities generated during the processing study. Recoveries of a mixture of imidacloprid and its guanidine metabolite spiked into control sugarbeets, fine sugar, molasses, and dried pulp at 0.2 ppm ranged from 82% to 114%. The petitioner provided adequate supporting chromatographic data for this study to allow independent verification of the results. The petitioner claims a 0.1 ppm LOQ; however, review of the supporting chromatographic data confirms a 0.05 ppm LOQ and a 0.01-02 ppm MDL for the sugarbeets and the sugarbeet processed commodities. UARs, while present, are not a problem in the rac sugarbeets, the molasses, fine sugar, and dried pulp samples.

No total imidacloprid residues were detected in any of the control and treated rac sugarbeet samples to the LOQ of 0.1 ppm. However, review of the supporting chromatograms indicates there are total imidacloprid residues in the rac sugarbeets near 0.05 ppm. When these sugarbeets were processed into fine sugar, molasses, and dried pulp the residues in the fine sugar were non-detected, thus no FAT is necessary for sugar. 0.34 ppm total imidacloprid was detected in molasses which indicates a concentration factor near 5X, not 2X as the petitioner claims. No total imidacloprid residues were detected in the dried beet pulp to <0.1 ppm; however, review of the supporting chromatogram indicates total imidacloprid residues present near 0.05 ppm. The petitioner will need to recalculate all total imidacloprid residues at and above the MDL so that we can determine the proper concentration/decline factor for each sugarbeet processed commodity.

The petitioner has conducted an adequate sugarbeet processing study using sugarbeets bearing detectable residues following an exaggerated 2.68X imidacloprid application to the seeds. However, the petitioner needs to present a revised final report recalculating the results based on a 0.05 ppm LOQ and a 0.01-0.02 ppm MDL. Judgement is deferred on the results of this imidacloprid sugarbeet processing study until we have reviewed the recalculated results and the petitioner's revised conclusions. CBTS expects that there are real residues of total imidacloprid in dried sugarbeet pulp which may required a FAT. CBTS points out that we may not require tolerances on this processed commodity if there is a small concentration factor and we are dealing with low level residues as we do not consider this to be a real concentration due to possible sample variations and/or to the residue analytical method's ability to accurately distinguish between numbers. If a FAT is required for sugarbeet pulp, then it should be for sugarbeet pulp (wet and dried) and be based on the concentration factor for dried pulp. We also expect that the FAT for imidacloprid

in molasses will be significantly higher requiring a revised Section F.

MAGNITUDE OF THE RESIDUE - MEAT/MILK/POULTRY/EGGS

No new ruminant or poultry feeding studies were submitted with this petition. The registrant has presented ruminant and poultry imidacloprid feeding studies. These studies have been previously reviewed in PP#s 3F4169 and 3F4231 (see memoranda by F. Griffith dated Sept. 21, 1993, and June 22, 1994).

In summary, for the ruminant feeding study 3 groups of 4 dairy cows were fed imidacloprid, per se, at levels of 5, 15, and 50 mg/kg in their feed for 28 consecutive days. The bovine feed items associated with this petition are barley grain [88% dry matter] up to 80% in beef cattle and up to 60% in dairy cattle diets, barley bran [88% dry matter] up 50% in beef cattle and up to 20% in dairy cattle diets, barley forage [30% dry matter] up to 30% in beef cattle and up to 75% in dairy cattle diets, barley hay [88% dry matter] up to 25% in beef cattle and up to 60% in dairy cattle diets, barley straw [89% dry matter] up to 15% of beef cattle diets and up to 10% of dairy cattle diets, and barley flour [88% dry matter] up to 20% in both beef and dairy cattle diets. Sugar beet leaves [23% dry matter] can be feed to beef cattle up 20% of the diet and up to 10% in dairy cattle diets. Molasses [25% dry matter] from sugar beets can be fed to both beef and dairy cattle up to 10% of their diets. Wet sugar beet pulp [30% dry matter] can be fed to both beef and dairy cattle at up to 35% of the diet while dried beet pulp [88% dry matter] can be fed to beef cattle up to 20 % and to dairy cattle at up to 25% of the diet. Grain sorghum [86% dry matter] can be fed to beef cattle at up to 80% of the diet, but only up to 60% of dairy cattle diets. Sorghum forage [35% dry matter] can be fed to beef cattle up to 90% of their diets but only up to 75% of dairy cattle diets, while sorghum fodder/stover [88% dry matter] can be fed up to 20% to beef cattle and up to 10% to dairy cattle. Grain sorghum aspirated grain fractions [85% dry matter] can be fed up to 20% of both beef and dairy cattle diets. Wheat grain [89% dry matter] can be fed to beef cattle up to 60% of the diet and to dairy cattle up to 50% of the diet. Wheat forage [25% dry matter] is fed to beef cattle up to 30% of the diet and up to 65% in dairy cattle diets. Wheat hay [88% dry matter] can be fed to beef cattle up to 25% of the diet and up to 60% of dairy cattle diets. Wheat straw [88% dry matter] is fed to beef cattle up to 15% of beef cattle and to dairy cattle up to 10% of the diet. Wheat milled byproducts [88% dry matter] can be used in beef cattle diet up to 63% and up to 50% in dairy cattle diets. Wheat aspirated grain fractions [88% dry matter] can be used for beef and dairy cattle up to 20% of the diets. All of the dry matter percentages and the percentages of the feed items in bovine diets are from Table II (June 1994).

The correct calculation of bovine dietary burden includes the conversion of the dry matter diet percentages to the "as-fed" basis, using the moisture content of the feed item. The potential bovine dietary burden for each of these feed items is based on the proposed tolerance, percentage in the diet, and the percent dry matter in the particular feed item. The potential dietary burden for barley forage

in beef cattle diets is 1.2 ppm [0.3 {(% in diet}/0.3 {% DM}) X 1.2 {proposed tolerance} = 1.2 ppm] and 3 ppm in dairy cattle diets. The potential dietary burden for barley grain in beef cattle diets is 0.09 ppm and 0.07 ppm in dairy cattle diets. The dietary burden from barley straw in beef cattle diets is 0.03 ppm and in dairy cattle diets is 0.02 ppm. The potential dietary burden in beef cattle diets from sugar beet leaves is 0.09 ppm and 0.04 ppm in dairy cattle. The potential dietary burden from feeding sugar beet molasses to beef and dairy cattle is 0.08 ppm. The potential dietary burden from feeding grain sorghum to dairy cattle is 0.09 ppm and 0.07 ppm in dairy cattle diets. The sorghum forage potential dietary burden in beef cattle is 0.26 ppm and 0.21 ppm in dairy cattle diets. The potential dietary burden in beef cattle diets from feeding sorghum fodder/stover is 0.02 ppm and in dairy cattle diets is 0.01 ppm. The potential dietary burden from feeding treated wheat grain in beef cattle diets is 0.07 ppm and 0.06 ppm in dairy cattle diets. The wheat forage potential dietary burden in beef cattle diets is 8.4 ppm and 16.8 ppm [0.65 {% in diet}/0.25 {% DM} X 7 {proposed tolerance} = 18.2 ppm] in dairy cattle diets. The potential dietary burden from feeding wheat straw to beef cattle is 0.05 ppm and 0.03 ppm in dairy cattle.

The registrant's worst case diet, while highly improbable, but in which he claims none-the-less maximizes the potential imidacloprid exposure, include grape pomace at 40% (2.8 ppm), raisin waste at 10% (0.7 ppm), potatoes at 30% (0.75 ppm), and cottonseed at 20% (0.14 ppm). We agree with the petitioner that 100% of the bovine diet can be treated with imidacloprid from the feed items in this petition and in co-pending petitions. While the registrant's worse case dietary burden at 4.4 ppm is lower then we expect from the total imidacloprid residues in bovine feed items (calculated on a % dry matter basis) we agree that 5 mg/kg or ppm was a reasonable 1X dose. Our estimate of a possible maximum imidacloprid dairy cattle dietary burden is around 22 ppm from a highly improbable diet of 65% wheat forage (18.2 ppm), 20% wet tomato pomace (2.7 ppm), and 15% culled potatoes (1.1 ppm) and a beef cattle dietary burden around 9.6 ppm from a highly improbable diet of 75% cull potatoes (5.6 ppm) and 25% wet tomato pomace (<4 ppm).

Milk was collected twice daily and at sacrifice liver, kidney, muscle, and fat were collected and analyzed. Maximum total imidacloprid residues in milk from the 5 mg/kg dose were 0.023 ppm and from the 15 mg/kg dose were 0.055 ppm. Total imidacloprid residues in fat were detected only from the 50 mg/kg dose at 0.079 ppm. No total imidacloprid residues were detected in muscles from the 5 mg/kg dose and the maximum residues in muscle from the 50 mg/kg dose were 0.192 ppm. In liver the maximum total imidacloprid residues from the 15 mg/kg dose were 0.168 ppm. Total imidacloprid residues in ruminant kidney were 0.032 ppm from the 5 mg/kg dose and 0.106 ppm from the 15 mg/kg dose.

In the poultry feeding study 3 groups of 12 laying hens were fed imidacloprid, per se, at levels of 2, 6, and 20 mg/kg in their diets for 30-32 consecutive days. The poultry feed items associated with this petition are barley grain up to 75% of the diet, barley bran up to 10% and barley flour up to 20% of the diets, wheat grain up to 82%

of the poultry diet and wheat milled byproducts up to 50% of the diets, and grain sorghum up to 80% of the diet. All of the percentages of the feed items in poultry diets are taken from Table II (June 1994). The correct calculation of poultry dietary burden is on the "as-fed" basis. The potential poultry dietary burden for each of these feed items is based on the proposed tolerance and the percentage in the diet for the particular poultry feed item.

The potential poultry dietary burden from barley grain is 0.075 ppm [0.75 {% in the diet} X 0.1 {proposed tolerance} = 0.075 ppm]. The potential poultry dietary burden from feeding of treated wheat grain is 0.082 ppm and from grain sorghum is 0.08 ppm. The registrant's worst case poultry diet, that is highly improbable, but which he claims maximizes potential imidacloprid exposure is approximately 1.62 ppm and includes grape pomace at 8% (0.56 ppm), spring cereal grains (not specified) at 50% (0.025 ppm), grain dust at 4% (0.002 ppm), potatoes at 30% (0.75 ppm), cottonseed oil (soapstock) at 5% (0.175 ppm), and cottonseed meal at 3% (0.175 ppm). Based on Table II (June 1994) we now agree that with the poultry feed items in this petition 100% of the poultry feed items will be treated with imidacloprid. Our revised dietary burden is higher at 2.45 ppm based on the total imidacloprid residues in poultry feed items in this and in co-pending petitions. We agree that 2 ppm (or mg/kg) is a reasonable 1X poultry feeding dose.

Eggs were collected twice daily and at sacrifice liver, muscle, and fat were collected and analyzed. Maximum total imidacloprid residues in eggs from the 2 mg/kg doses were <0.02 ppm while from the 6 mg/kg dose were 0.056 ppm. No total imidacloprid residues were detected in poultry fat from any of the 3 doses. In poultry muscle total imidacloprid residues were non-detected or <0.02 ppm from the 2 mg/kg dose while from the 6 mg/kg dose the maximum residue was 0.072 ppm. Total imidacloprid residues in poultry liver were 0.042 ppm from the 2 mg/kg dose and 0.159 ppm from the 6 mg/kg dose.

Based on the results of imidacloprid bovine and poultry feeding studies, CBTS concludes that finite residues will occur in meat, milk, poultry, and eggs from the feeding of imidacloprid treated racs or their processed feed items when Admire®, and/or Gaucho® is used as directed in seed treatments. Secondary imidacloprid tolerances are necessary since these feeding studies show transfer of residues from the treated feed items to meat, milk, poultry, and eggs. Adequate total imidacloprid secondary tolerances have been proposed in co-pending petitions at 0.1 ppm in milk, 0.3 ppm in meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep, 0.02 ppm in eggs, and at 0.05 ppm in meat, fat, and meat by-products of poultry.

Since there are major livestock feed items associated with the racs and their processed feed items in this petition the petitioner will need to propose in a revised Section F the same total imidacloprid secondary milk, meat, poultry and eggs tolerances that have been proposed in the co-pending petitions currently in reject status.

HARMONIZATION OF TOLERANCES

An INTERNATIONAL RESIDUE LIMIT STATUS SHEET (IRL) is attached to this review. Since there are no Mexican, Canadian, or Codex MRLs/ tolerances for sorghum, wheat, barley, and sugar beets and their processed commodities, compatibility is not a problem at this time.

cc:R.F.,Circu.,Reviewer(FDG), PP#4F4337.
7509C:CBTS:Reviewer(FDG):CM#2:Rm804Q:305-5826:FDG:8/18/94:edit:fdg:9/8/94.
RDI:SecHd:RSQuick:9/12/94:ActBrSrSci:MTFlood:9/8/94.

INTERNATIONAL RESIDUE LIMIT STATUS

7/25/94
J. Rees

CHEMICAL Imidacloprid (Gaucho®)

CODEX NO. ____

CODEX STATUS:

☑ No Codex Proposal Step 6 or above

Residue(if Step 8): ____

Crop(s)	Limit (mg/kg)

CANADIAN LIMITS:

☑ No Canadian limit

Residue: ____

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 4F 4337

RCB Reviewer F.D. Griffith Jr. 7/22/94

Residue: Combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, calculated as imidacloprid

Crop(s)	Limit (mg/kg)
Wheat forage	7
wheat straw	0.3
wheat grain	0.1
Barley forage	1.2
Barley Straw	0.2
Barley grain	0.1
Sorghum forage	0.1
Sorghum straw	0.1
Sorghum grain	0.1
Sugar beet tops	0.1
Sugar beet roots	0.1
Sugar beet molasses	0.2

MEXICAN LIMITS:

☑ No Mexican limit

Residue: ____

Crop(s)	Limit (mg/kg)

NOTES:

* 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine

Form revised 1986

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R059893

Chemical:	**Imidacloprid**
PC Code:	**129099**
HED File Code	**11000 Chemistry Reviews**
Memo Date:	**09/14/94 12:00:00 AM**
File ID:	**DPD201536; DPD201543; DPD201634; DPD201635; DPD207206**
Accession Number:	**412-04-0047**

HED Records Reference Center
04/05/2004